IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SPINAL GENERATIONS, LLC, Plaintiff, v. DEPUY SYNTHES, INC., SYNTHES USA, LLC, SYNTHES USA PRODUCTS, LLC, AND DEPUY SYNTHES SALES, INC., Defendants.	Civil Action No. 22-1368-CFC

MEMORANDUM

Section 112(a) of the Patent Act requires that every patent "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112(a). Patent practitioners refer to this requirement as enablement. To comply with § 112(a), a patent's "specification must enable the full scope of the invention as defined by its claims." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610 (2023). This enablement requirement lies at the heart of the dispute before me.

The Plaintiff in this case, Spinal Generations, LLC (Spinal), has accused Defendants DePuy Synthes, Inc., Synthes USA, LLC, Synthes USA Products, LLC, and DePuy Synthes Sales, Inc. (together, DePuy) of infringing claims 1–3, 8, and 14 of U.S. Patent No. 8,808,337 (the #337 patent) and claims 1–9 and 11 of U.S. Patent No. 7,575,572 (the #572 patent). D.I. 49 ¶¶ 130–135, 174–179; *see* D.I. 149. For each patent, claim 1 is the sole independent asserted claim. *See* D.I. 153 ¶¶ 1, 8; D.I. 178 ¶¶ 1, 8.

Pending before me is DePuy's Motion for Summary Judgment of Invalidity for Lack of Enablement. D.I. 149.[1] A court must grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The parties agree that there are no disputed material facts and that the resolution of the motion turns on my answer to the legal question of whether the patents enable an artisan of ordinary skill to practice the "full scope" of the inventions recited in claim 1 of each of the patents. *See* D.I. 151 at 19; D.I. 174 at 22.

The patents claim inventions for use by orthopedic surgeons. Both patents are titled "Method and Device for Delivering Medicine to Bone." D.I. 49-1 at 114,

[1] I reviewed and considered in deciding the pending motion the parties' briefing filed in support and opposition of both that motion (D.I. 149) and Spinal's motion for partial judgment (D.I. 154). D.I. 151; D.I. 174; D.I. 197; D.I. 158; D.I. 182; D.I. 194.

43. Claim 1 of the #337 patent claims "a system for delivering a substance to a bone" that "compris[es]," among other things, "a second position wherein [an] insert provides a delivery pathway for [a] substance *between at least one end of the insert and a portion of the bone*." D.I. 49-1 at 151 (emphasis added). Claim 1 of the #572 patent claims a "device for delivering a substance to a bone" that "compris[es]," among other things, a "second position wherein [an] insert provides a delivery pathway for [a] substance *between at least one end of [a] bone screw and [] at least one bone-screw fenestration*." D.I. 49-1 at 61 (emphasis added).

The parties stipulated that in both clauses (which I will refer to as "the second position clauses") the phrase "at least one end" means "one or both ends." D.I. 147 at 1; D.I. 153 ¶¶ 3, 10; D.I. 185 ¶¶ 3, 10. The previous judge who presided over the case adopted that construction; and therefore, by stipulated order, claim 1 of the #337 patent covers a system that has, among other things, an insert that provides a delivery pathway for a substance between (1) one or both ends of the insert and (2) the bone, and claim 1 of the #572 patent covers a device with an insert that provides a delivery pathway for a substance between (1) one or both ends of a bone screw and (2) a bone-screw fenestration. *See* D.I. 147 at 1.

It is undisputed that both the "insert" and the "bone screw" recited in the claims' second position clauses have two ends—a proximal end and a distal end. *See* D.I. 151 at 17; D.I 174 at 23; D.I. 153 ¶¶ 3–5, 10–12; D.I. 178 ¶¶ 3–5, 10–12.

The proximal end is the end closer to the surgeon when the surgeon employs the claimed inventions to deliver a substance to the patient's bone. D.I. 151 at 17–19 & n.17; D.I. 158 at 4–5. The distal end is the end closer to the patient's bone. D.I. 151 at 17–19 & n.7; D.I. 158 at 4–5. Between the two ends are "fenestrations" along the bone screw: holes through which the substance exits to reach the patient's bone. D.I. 49-1 at 57–58; D.I. 158 at 4–5.

It is also undisputed that the #337 patent teaches a delivery pathway between the proximal end of the insert and the bone and that the #572 patent teaches a delivery pathway between the proximal end of the bone screw and a bone-screw fenestration. D.I. 151 at 17–19; D.I. 158 at 4–5, 10. And finally, it is undisputed that neither of the patents' written descriptions teaches, without undue experimentation, a delivery pathway between the distal end of the insert and the bone (in the case of the #337 patent) or between the distal end of the bone screw and a bone-screw fenestration (in the case of the #572 patent). *See* D.I. 151 at 17–19; D.I. 174 at 23–24; D.I. 153 ¶¶ 4–5, 11–12; D.I. 178 ¶¶ 4–5, 11–12.

DePuy argues that because the #337 patent does not teach a skilled artisan how to make or use a system with a delivery pathway between the distal end of the insert and the bone and because the #572 patent does not teach a skilled artisan how to make or use a device with a delivery pathway between the distal end of a bone screw and the bone, the patents do not teach the full scope of the claimed

inventions and therefore they are invalid for lack of enablement as a matter of law. I agree. Section 112(a), *Amgen*, and Federal Circuit case law are clear in this regard.

Section 112(a) states that every patent "*shall* contain a written description *of the invention*, and of the manner and process of making and using it, *in such full, clear, concise, and exact terms as to enable any person skilled in the art* to which it pertains, or with which it is most nearly connected, *to make and use the same*." § 112(a) (emphasis added). A patent's "invention [i]s defined by its claims," and a patent does not meet the enablement requirement if does not teach "the full scope" of the claimed invention. *Amgen*, 598 U.S. at 610–11. "Full" means "containing as much or as many as is possible or normal," "complete especially in detail, number, or duration," and "having all distinguishing characteristics." *See Full*, Merriam-Webster's English Dictionary (ed. 2024). The asserted patents do not teach the full scope of the inventions covered by the asserted claims because the #337 patent does not teach a pathway between both ends of the insert and the bone, and the #572 patent does not teach a pathway between both ends of the bone screw and a bone-screw fenestration. The asserted claims are therefore invalid as a matter of law for lack of enablement. *See Trs. of Bos. Univ. v. Everlight Elecs. Co.*, 896 F.3d 1357, 1363–64 (Fed. Cir. 2018) (invalidating claim for lack of enablement because performing one of six "referenced permutations" "is

impossible"); *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1364–66 (Fed. Cir. 2023) (invalidating claims for failure to enable a subset of "undisclosed but claimed antibodies"); *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1381–84 (Fed. Cir. 2012) (invalidating claims for lack of enablement because the specification only enables "a small subset of the claimed range"); *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008) (invalidating claims because the patent did not enable one of two claimed embodiments); *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1378 (Fed. Cir. 2007) (same); *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1243–44 (Fed. Cir. 2003) (same); *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1281–85 (Fed. Cir. 2007) (same); *see also MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 368–69 (D. Del. 2019) (Stark, J.) ("[T]he full scope of a claim is not enabled when there is an embodiment within the claim's scope that a person of ordinary skill, reading the specification, would be unable to practice without undue experimentation.").

Spinal could have claimed an invention that covered "a second position wherein the insert provides a delivery pathway for the substance between *the proximal end* of the insert and a portion of the bone." It also could have claimed an invention that covered "a second position wherein the insert provides a delivery pathway for the substance between *one end* of the insert and a portion of the bone."

But instead, it made a strategic decision to broaden the scope of the claimed invention to cover "a second position wherein the insert provides a delivery pathway for the substance between *at least* one end of the insert and a portion of the bone," and then it made a strategic decision to stipulate in this case that "at least one end" means "one *or both* ends." Such strategic decisions (and word choices to implement those decisions) have consequences in patents and in litigation. "The more one claims, the more one must enable." *Amgen*, 598 U.S. at 610.

Because the #337 patent undisputably does not teach a delivery pathway between the distal end of the insert and the patient's bone, it does not teach a delivery pathway from both ends of the insert and, therefore, does not teach the full scope of the claimed inventions. That deficiency makes it invalid for lack of enablement as a matter of law. The #572 patent is similarly invalid, as it undisputably does not teach a delivery pathway between the distal end of the bone screw and a bone-screw fenestration, and thus does not teach a delivery pathway between both ends of the bone screw and a bone-screw fenestration.

Spinal insists that "the addition of the 'at least' language to claim 1—which yields the 'one or both ends' construction—*did not expand the scope of the claim at all*." D.I. 174 at 24 (emphasis in the original). But, of course, it did—at least (pardon the pun) if the words "at least" are to have any meaning. By adding the

words "at least" to claim 1 of the #337 patent, Spinal broadened the claim's second position clause to cover both (1) an insert that delivers a substance to the bone from only one end of the insert *and* (2) an insert that delivers medicine to the bone from both ends of the insert. *See Z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1349 (Fed. Cir. 2007) ("[U]se of the phrase 'at least one' means that there could be only one or more than one.") (quoting *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed. Cir. 1999)). And by adding the words "at least" to claim 1 of the #572 patent, Spinal broadened that claim's second position clause to cover both (1) an insert that delivers a substance to a bone-screw fenestration from only one end of the bone screw *and* (2) an insert that delivers medicine to a bone-screw fenestration from both ends of the bone screw.

Spinal also argues that it would be "utterly impractical" and "nonsensical" to deliver a substance (i.e., bone cement) to the bone from the distal end of the insert. D.I. 174 at 23. That may be true, but it begs the question—why then did Spinal include the words "at least" in the asserted claims? Having chosen to claim "at least one end" instead of "one end" of the insert in the #337 patent, Spinal increased the scope of its claims to cover second positions with inserts that provide delivery pathways between *both ends* of the insert and the bone. And having chosen to claim "at least one end" instead of "one end" of the bone screw in the #572 patent, Spinal increased the scope of its claims to cover second positions with

inserts that provide delivery pathways between *both ends* of the bone screw and a bone-screw fenestration. It thus enabled itself (again, pardon the pun) through the exercise of the monopoly rights that come with a patent to exclude others from making and using devices and systems that employ second positions with pathways between both ends of the insert and bone and both ends of the bone screw and a bone-screw fenestration. But because the patents do not enable those pathways, the claims in which those pathways are elements are invalid as matter of law. *See Amgen*, 598 U.S. at 613 ("[T]he more a party claims, the broader the monopoly it demands, the more it must enable.").

Finally, Spinal argues that DePuy "waived" its enablement defense "by failing to properly raise it in [its] Invalidity Contentions." D.I. 174 at 22. But in each of its initial invalidity contentions served in June 2023, updated contentions served in August 2023, and final contentions served in January 2024, DePuy quoted the second position clauses of the #337 and #572 patents and identified them as "claim elements that lack enablement and, accordingly, [render] the claims in which they appear [ ] invalid." D.I. 183, Ex. A at 42–43; D.I. 183, Ex. B at 43–44; D.I. 183, Ex. D at 50–52. Moreover, in its updated and final contentions, DePuy italicized for emphasis "*at least one end of the bone screw*" and "*at least one end of the insert*" in those clauses. Thus, Spinal cannot credibly say that it lacked notice of the invalidity-for-lack-of-enablement defense DePuy has made in

its summary judgment motion.

Accordingly, for the reasons stated above, I will grant DePuy's Motion for Summary Judgment of Invalidity for Lack of Enablement (D.I 149).

The Court will issue an Order consistent with this Memorandum.

Colm F. Connolly
Chief Judge